Original Article

Study the impact of clinical pharmacist provided patient counseling on hypertension management in rural Indian population

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ABSTRACT

Objective: To assess the patient counseling provided by clinical pharmacist on hypertension management in a rural population.
Materials and Methods: It is a prospective, randomized and interventional study conducted over a period of 9 months. The envelop randomization method was adopted to group the patients into control and intervention.
Results: A total of 200 hypertensive patients were approached. Out of which 95 patients consented to participate and only 90 patients completed the study. Among these hypertensive patients, 65 were men and 25 women. The knowledge, attitude and practices (KAP) score at baseline was 47.76 ± 7.33 in control and 47.20 ± 5.82 in the intervention group, respectively. The same in the third follow-up was found to be 35.96 ± 3.54 in control and 31.56 ± 1.95 in the intervention group, respectively. The *P* values were 0.691 at the baseline, 0.060 in first follow-up, 0.001 in second follow-up, and < 0.001 in third follow-up. Mean score of various domains (recall, access, and regimen screens) to medication adherence showed a significant improvement. The *P* values of adherence to medication regimen at baseline and third follow-up was 0.974 and 0.329, respectively. The overall comparison of quality of life (QoL) scores showed a large improvement (suggestive significance) from baseline ($P = 0.494$) to final follow-up ($P = 0.51$).
Conclusion: This study shows that the involvement of clinical pharmacists in rural hypertension management has a positive impact in creating awareness about the disease, drugs and its usage, and its effect on quality of life.

INTRODUCTION

Cardiovascular diseases have emerged as an important health problem in India. High blood pressure (BP) is a major risk factor for health and better control can lead to the prevention of 1.5 million annual deaths in India. Epidemiological studies demonstrate that prevalence of hypertension is increasing rapidly among the urban and rural population of India.[1,2]

In chronic diseases like hypertension, the patient needs to take lifelong medication with single or two drugs while some may be on polypharmacy. In the Indian rural setup, majority of the patients are illiterate and have poor health literacy which may lead to misuse of drugs, improper usage, drug-induced disorders or failure of ongoing treatment. In order to overcome this problem, rational use of medication process has to be adopted by introducing "patient counseling".[2]

Repeated interaction with patients or counseling either verbally or nonverbally or both helps to increase

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medication adherence behavior, minimize drug-related problems, reduce the cost by correct maintenance of health and increase patient satisfaction.[3] The pharmacist has noteworthy/immense responsibility in counseling the patients with chronic illnesses like hypertension.[4]

The goals of chronic disease care were to enhance functional status, minimize distressing symptoms, prolonged life through secondary prevention and enhance quality of life (QoL). Understanding the levels of knowledge, attitude and practice will allow for a more efficient process of awareness creation among the people and illustrate the areas in which the patient must need an education and training.[5-11]

Brief Medication Questionnaire (BMQ), a medication adherence measurement questionnaire, is used to assess the reported medication adherence behavior of patients. BMQ consists of four sections: Regimen screen, belief screen, recall screen and access screen. All these BMQ screens consisted of a positive and negative screen.[12]

People with hypertension have a poor QoL than normotensives. Therefore, QoL (i.e. SF-36v2™ Health Survey questionnaires) measurements are being increasingly recognized as an important tool for the assessment of medical outcomes of chronic diseases.[13]

Therefore, the present study was undertaken in rural hypertensive patients to know the knowledge, attitude and practices (KAP), medication adherence, and QoL.

MATERIALS AND METHODS

Study site

The study was conducted in the medicine unit of Adichunchanagiri Hospital and Research Centre, B. G. Nagara, Mandya District, Karnataka, India which is a rural tertiary care 750-bedded teaching hospital.

Study design

It is a prospective randomized controlled study. The envelop randomization technique was used to group the patient into control and intervention.

Study period

The study was conducted over a period of 9 months starting from June 2010 to February 2011.

Ethical approval

Ethics committee approval was taken (Ref. no: AIMS/EC/601/2010-11, Dated: June 22, 2010) prior to the study from institutional ethics committee (Adichunchangiri Institute of Medical Sciences, B.G.Nagar, Mandya District, Karnataka, India).

Study criteria

Inclusion criteria

- Hypertensive patients above 18 years of age.
- Hypertension alone or with less than 4 co-morbidities. For example, hypertension (HTN) with diabetes mellitus (DM), asthma and chronic obstructive pulmonary disease (COPD).

Exclusion criteria

- Pregnant/lactating hypertensive patients.

The hypertensive patients visiting the medicine department of tertiary care hospital (AH and RC: Adichunchanagiri Hospital and Research Centre) were enrolled after taking their consent and divided into two groups, that is, control and interventional group by envelope randomization technique. The enrolled patients were briefed about the study and informed (orally, telephonically as well as by envelop reminders) to come for the first follow-up after 1 month from the date of the enrolment and thereafter, every 30 days for the remaining two follow-ups to know their health status. Education materials like patient information leaflets on disease and drugs (amlodipine, atenolol, enalapril, losartan, metoprolol, nifedipine, ramipril, verapmil) were prepared in English and local language, that is, Kannada and validated. Patient satisfaction questionnaire was also prepared by consulting the hospital clinical pharmacists. The leaflets were distributed/given to the patients for better disease management. The disease information leaflet contained information like definition of disease, reasons, signs, symptoms, and management. The drug information leaflet consisted of drug name, brand name, dose and usage information, side effect, storage, and precaution.

The control and intervention group patients were interviewed and their socio-demographic details (e.g., previous history, income, habits, previous medication, etc.) were collected and entered in a well-designed data collection form along with systolic and diastolic blood pressure (SBP and DBP), and body mass index (BMI). Control group patients were not counseled at the baseline but, their KAP, Medication adherence (BMQ) and QoL were assessed using their respective questionnaires. The answers given by them were recorded and the same method was carried out in first, second, and third follow-up. The control group was counseled at the third follow-up. Whereas, the

intervention group patients were counseled (verbal and nonverbal/written) on various aspects like disease, drugs, life style modifications (e.g., low salt intake, exercise/walking, etc.) and their management during all the three follow-ups, and patient satisfaction towards the clinical pharmacist who provided patient counseling services was collected in a questionnaire. In each follow-up and at the baseline, the patient's SBP and DBP were noted/measured in both the groups.

Statistical methods

Statistical analysis methods like, level of significance (5%) for continuous measurements was done with Mean ± S.D. (Min-Max), and categorical measurements with Number (%). Student's *t*-test (two tailed, independent) was used for continuous scale between two groups. Intergroup analysis was performed on metric parameters. Mann–Whitney U test was used to find the significance between two groups' parameters on non-interval scale. Pearson's correlation method used between KAP, BP with QOL analysis.

RESULTS

A total of 200 patients were approached during the study period and were informed about the study and its procedure briefly. Out of which only 95 patients agreed to participate. The remaining, that is, 105 people were not interested in the study due to unknown reasons (e.g. distance from study site, unable to come for follow-up, financial problems, etc.). Out of 95 patients, 90 completed all the three follow-ups and 5 dropped out.

Table 1 shows the distribution of sociodemographic details. There were 34 (75.6%) males in control and 31 (68.9%) in intervention group. Similarly, there were 11 (24.4%) female patients in the control and 14 (31.1%) in the intervention group. Majority of patients belonged to the age group of 61-70 years, that is, 17 (37.8%) in control and 15 (33.3%) in intervention group; followed by 51-60 years, that is, 12 (26.7%) in control and 11 (24.4%) in intervention group. The smoking habit of the study patients showed that there were 16 and 10 smokers in control and intervention group, respectively. Overall, the smoking habit was similar in both the groups. The percentage of alcohol consumption habit among the study patients was 17.8 and 22.2 in control and intervention group, respectively.

Figure 1 and Table 2 shows the KAP score. The *P* values at baseline, first, second, and third follow-up was found to be 0.691, 0.060 (suggestive significance),

Table 1: Sociodemographic details

	Control group		Intervention group	
	Number	%	Number	%
Gender				
Male	34	75.6	31	68.9
Female	11	24.4	14	31.1
Total	45	100.0	45	100.0
Age (years)				
18-20	0	0.0	0	0.0
21-30	1	2.2	1	2.2
31-40	2	4.4	3	6.7
41-50	4	8.9	5	11.1
51-60	12	26.7	11	24.4
61-70	17	37.8	15	33.3
71-80	8	17.8	9	20.0
81 and above	1	2.2	1	2.2
Total	45	100.0	45	100.0
Smoking				
Smoker	16	35.6	10	22.2
Non-smoker	26	57.8	25	55.6
Past smoker	3	6.7	10	22.2
Total	45	100.0	45	100.0
Alcoholic habit				
Alcoholic	8	17.8	10	22.2
Non-alcoholic	33	73.3	31	68.9
Past alcoholic	4	8.9	4	8.9
Total	45	100.0	45	100.0

Table 2: Comparison of KAP score in two groups of patients

KAP	Control group (Mean±SD)	Intervention group (Mean±SD)	*P* value
Baseline	47.76±7.33	47.20±5.82	0.691
First follow-up	40.02±5.83	38.24±2.30	0.060 (*)
Second follow-up	37.69±5.99	34.53±2.01	0.001 (***)
Third follow-up	35.96±3.54	31.56±1.95	<0.001 (***)

KAP=Knowledge, attitude and practices. *Slightly significant, **Moderately significant; ***Strongly significant

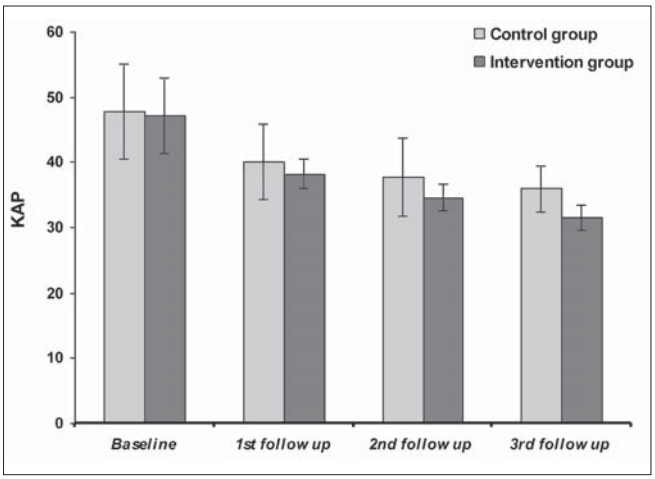

Figure 1: Comparison of KAP score in two groups of patients

0.001, and < 0.001 (strongly significant), respectively. This clearly showed that there is a positive impact of pharmacist provided counseling.

Table 3 shows the medication adherence means scores of various domains like regimen, recall, belief and access screens in which a very good improvement can be observed. In which the *P* values of recall (baseline-0.439, first-0.001, second-0.030, and third-1.000) and access screens (baseline-0.696, first-0.018, second-0.089, and third-0.004) were strongly significant.

Table 4 shows the SBP of control and intervention groups with a significant improvement in the *P* values from the baseline (0.64) to third follow-up (0.021). Similarly, the *P* values of DBP showed a good improvement from 0.140 at baseline to 0.604 at third follow-up.

Table 3: Comparison of medication adherence (mean score) in two groups of patients

Medication adherence	Control group	Intervention group	*P* value
Regimen screen			
Baseline	4.38	4.4	0.974
First follow-up	1.51	2.1	0.218
Second follow-up	1.51	1.4	0.371
Third follow up	1.31	1.2	0.329
Belief screen			
Baseline	0	0	0
First follow-up	0	0	0
Second follow-up	0	0	0
Third follow-up	0	0	0
Recall screen			
Baseline	0.3	0.2	0.439
First follow-up	0.6	0.2	0.001 (***)
Second follow-up	0.5	0.3	0.030 (**)
Third follow-up	0.2	0.2	1.000
Access screen			
Baseline	0.6	0.7	0.696
First follow-up	1.4	1.1	0.018 (**)
Second follow-up	1.3	1.4	0.890
Third follow-up	1.5	1.8	0.004 (***)

*Slightly significant, **Moderately significant, ***Strongly significant

Table 4: Comparison of BP between two groups

BP	Control group (Mean±SD)	Intervention group (Mean±SD)	*P* value
SBP (mm Hg)			
Baseline	160.04±24.45	157.87±27.81	0.694
First follow-up	145.78±17.90	146.00±15.43	0.950
Second follow-up	137.16±11.02	137.33±9.39	0.935
Third follow-up	127.69±7.53	130.89±5.14	0.021 (**)
DBP (mm Hg)			
Baseline	97.42±13.13	93.82±9.49	0.140
First follow-up	89.87±5.47	88.4±3.97	0.149
Second follow-up	85.24±3.28	84.67±3.86	0.446
Third follow-up	81.07±2.85	81.38±2.82	0.604

BP=Blood pressure, SBP=Systolic BP, DBP=Diastolic blood pressure.
*Slightly significant, **Moderately significant, ***Strongly significant

Table 5 shows comparison among QoL scores of various domains like physical function, role function, body pain, general health, vitality, social function, and role emotional score. *P* values were found to be statistically significant when compared from baseline to third follow-up. The physical function (*P* values: Baseline-0.679, first-0.045, second-0.002, and third- <0.001) and mental health score (*P* values: Baseline-0.366, first-0.036, second-0.021, and third- <0.002) showed a very good and significant improvement from baseline to each follow-ups. The mental state and physical condition are strongly associated with the maintenance of QoL. This clearly showed that pharmacists play a very important key role in disease maintenance.

Table 6 shows the overall comparison of QoL score in two groups. A greater improvement was seen in the intervention group than the control, that is, from a $P = 0.494$ at baseline to $P = 0.51$* at third follow-up. However, in second follow-up the overall QoL showed a more significant *P* value, that is, 0.08*** than other follow-ups.

Table 7 shows that the patients belonging to the intervention group were completely satisfied with pharmacist provided patient counseling.

DISCUSSION

Patient counseling is one of the method/process for improving the rational use of medications which promotes awareness among people to learn about medicines and their safe use; this in turn minimizes the risks associated with drugs.

Sociodemographic parameters

In our study, there were 65 male and 25 female patients [Table 1]. This may be because of the male patients' working environment, social habits, genetic influences, etc., Most of the patients were belonged to the age group of 51-70 years. The national demographics of hypertension survey showed that hypertension is highly prevalent among patients which are ≥ 50 years. The age group of 61-80 years and above had more number of hypertensive patients, that is, a total of 51 in both the groups (control and intervention) followed by the age group of 51-60, which had 26 hypertensive patients from both the groups. As mentioned earlier, this shows that the

Table 5: Comparison of QoL scores in two groups

QoL score	Control group (Mean±SD)	Intervention group (Mean±SD)	*P* value
Physical function			
Baseline	43.89±15.37	42.56±15.8	0.679
First follow-up	48.89±16.06	43.78±13.02	0.045 (**)
Second follow-up	53.89±16.72	45.78±13.90	0.002 (***)
Third follow-up	66.00±15.90	73.33±12.97	<0.001(***)
Role function			
Baseline	40.00±29.39	32.22±24.20	0.192
First follow-up	34.44±24.01	31.67±16.34	0.705
Second follow-up	45.56±26.80	32.22±17.37	0.003 (***)
Third follow-up	41.11±25.65	47.22±17.86	0.036 (**)
Body pain			
Baseline	54.31±15.58	55.40±13.83	0.883
First follow-up	48.31±17.29	44.98±12.98	0.423
Second follow-up	51.87±14.69	46.89±8.63	0.108
Third follow-up	42.49±15.78	50.38±7.15	<0.001 (***)
General health			
Baseline	36.22±5.56	36.78±5.35	0.601
First follow-up	39.76±12.41	34.91±9.67	0.031 (**)
Second follow-up	41.56±12.29	37.13±9.13	0.060 (*)
Third follow-up	46.67±11.44	43.31±7.35	0.004 (***)
Vitality			
Baseline	42.44±7.88	42.22±8.30	0.951
First follow-up	45.22±13.31	38.33±9.35	0.004 (***)
Second follow-up	46.00±13.17	39.56±7.22	0.007 (***)
Third follow-up	45.11±11.55	42.11±7.65	0.136
Social functioning			
Baseline	53.16±14.88	52.67±12.65	0.708
First follow-up	49.53±15.53	49.51±7.98	0.957
Second follow-up	51.22±17.02	52.07±7.10	0.739
Third follow-up	54.84±15.17	51.76±8.38	0.215
Role emotional			
Baseline	45.22±27.83	40.76±27.58	0.456
First follow-up	42.04±26.14	43.58±18.81	0.421
Second follow-up	50.36±25.44	47.36±19.72	0.548
Third follow-up	51.82±23.31	57.18±15.58	0.123
Mental health			
Baseline	49.16±6.75	50.04±5.63	0.366
First follow-up	49.96±8.60	46.31±8.55	0.036 (**)
Second follow-up	51.73±10.83	47.29±7.40	0.021 (**)
Third follow-up	51.29±8.01	47.38±5.84	0.002 (***)

QoL=Quality of Life. *Slightly significant, **Moderately significant, ***Strongly significant

Table 6: Comparison of overall QoL scores in two groups

Overall QoL score	Control group (Mean±SD)	Intervention group (Mean±SD)	*P* value
Physical health (A)			
Baseline	43.31±11.26	41.73±9.97	0.427
First follow-up	43.11±11.82	38.47±9.66	0.027 (**)
Second follow-up	47.49±13.27	40.00±9.44	0.001 (***)
Third follow-up	48.04±13.24	50.91±7.69	0.017 (**)
Mental health (A)			
Baseline	45.20±8.83	44.47±7.59	0.724
First follow-up	45.16±10.64	42.49±8.07	0.163
Second follow-up	48.07±11.8	44.62±8.45	0.116
Third follow-up	49.87±11.24	48.27±6.41	0.280
Overall QoL			
Baseline	45.60±10.75	44.07±9.42	0.494
First follow-up	44.80±10.67	41.62±8.80	0.063 (*)
Second follow-up	49.07±12.00	43.56±9.17	0.008 (***)
Third follow-up	49.91±12.68	51.56±6.83	0.051 (*)

QoL=Quality of Life, *Slightly significant **Moderately significant, ***Strongly significant

Table 7: Patients' satisfaction for pharmacist provided patient counseling in intervention group. (Response: Yes/No)

Patient satisfaction	Intervention group (%)
Are you happy?	45 (100.0)
Are you satisfied with the amount of time spent?	45 (100.0)
Did the information provided was useful?	45 (100.0)
Do you need patient counseling in future?	45 (100.0)
Are you happy with the content of counseling?	45 (100.0)
Are you happy with the overall patient counseling process?	45 (100.0)

prevalence of hypertension is more among the elderly people. The study population showed a total of 26 active smokers and 18 alcoholics. However, overall smoking and alcoholic habits were same in both the control and intervention groups. Interestingly, this study shows that more hypertensive patients have absence of precipitating risk factors.[14,15]

Knowledge, attitude and practices

KAP are the important parts in disease management; this study gives a clear idea about the patients' knowledge regarding disease, drugs and its usage. Figure 1 and Table 2 shows the comparison of KAP between the control and intervention group, in which a statistically significant result was observed at the third follow-up. At entry level, KAP analysis found that patients had a poor perception about their disease. Their attitude and practice was below average, and they had a fair idea of the symptoms of hypertension. Repeated intervention with them had made changes in their KAP.[16-18]

Medication adherence and BP

At baseline, low medication adherence rate was observed among the enrolled patients when compared to three follow-ups. However, repeated counseling showed that improvement in medication adherence significantly reduced the SBP and DBP of both the groups. As most of the patients were illiterate it was

difficult for them to remember the name of the drug, but on repeated counseling they remembered it with the help of the strips, color, and covers of the medicines which made them adhere to their medication properly. There were few patients who missed the doses but their blood pressure was found to be under control. This may be the reason for increase in *P* values in diastolic when compare with the same of SBP. This study strongly suggested that there is a need of continuous education to the patients to improve their medication adherence towards disease management. The common reasons for non-adherence found in the enrolled patients were forgetfulness (regimen screen) and financial (access screen) problems.

Quality of life

QoL is a major concern in the overall health status of patients, where it shows a very good result within the medication adhered people. In some of the cases, QoL in certain domains showed an improvement. This study also showed that there was an altered QoL among some patients and the reasons were age, comorbidities, physical and mental status/psychological belief about the disease, etc., [Table 5 and 6].

The overall physical and mental health, and QoL results strongly suggest that there is a need of more and more education to the rural people. The overall physical health and QoL results were found to be positive only in third follow-up [Table 6].

The patient satisfaction questionnaire, about the services rendered by the pharmacist during patient counseling in the management of hypertension, showed maximum satisfaction within the intervention group. This strengthens the fact that there is a need for more and more clinical pharmacist services for the efficient management of chronic diseases.

CONCLUSION

This study showed that clinical pharmacist provided patient counseling has a strong positive impact in increasing the medication adherence behavior, prolonging life, and improving the QoL of rural hypertensive patients. This study also highlights that there is a need of patient counseling services for the rural population in chronic disease maintenance.

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